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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,803	12/02/2003	Thomas J. Maginot	22220-08626	4106
758	7590	12/14/2005		
FENWICK & WEST LLP SILICON VALLEY CENTER 801 CALIFORNIA STREET MOUNTAIN VIEW, CA 94041			EXAMINER PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TAL 15

<b>Office Action Summary</b>	Application No. 10/726,803	Applicant(s) MAGINOT, THOMAS J.	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-14 is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/8/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### ***Terminal Disclaimer***

The terminal disclaimers filed on September 30, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US-6,401,721, US-5,749,375, and US-5,571,167 have been reviewed and are accepted. The terminal disclaimers have been recorded.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7 and 9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/731,068 in view of Redtenbacher (US 4,817,847). Although the conflicting claims are not identical, they are not patentably distinct from each other because copending claim 1 is broader than present claim 7 except for the endoscope

used therein. However, Redtenbacher teaches that the use of an endoscope in similar methods was known. Therefore, it is the Examiner's position that it would have been obvious to use an endoscope in the method of claim 7 for the same reasons that Redtenbacher uses the same and in order to allow better viewing of the operation site.

With regard to claim 9, claim 1 is read on or anticipated by claim 9 alone. For this reason, these two claims are considered clearly obvious in view of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brewster (article entitled "Direct Reconstruction for Aortoiliac Occlusive Disease") in view of Ablaza (US 4,190,909). Brewster teaches side-to-end anastomosis of arteries with a blood-conveying conduit, but fails to teach doing so under substantially intact skin; see pages 674 to 676. However, Ablaza teaches that it was known to keep skin substantially intact because Ablaza keeps the skin substantially intact by using only an incision where the connection point is under completely intact skin. The terminology "substantially" of "substantially intact" is being treated as a broad term, which encompasses skin that has been cleanly incised with a scalpel, for example. Therefore,

it is the Examiner's position that it would have been *prima facie* obvious to implant the Brewster graft under "substantially intact skin" so that bleeding and trauma to the skin could be reduced and so that a clean barely visible scar would result upon healing.

With regard to claim 5, one of the anastomotic connections are made below the inguinal ligament, which is clearly shown in the figures, see Figures 55-6 D and 55-7.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster (US 4,366,819) in view of Loiterman (US 4,983, 165). Kaster discloses a medical procedure for connecting a blood vessel and blood conveying conduit extravascularly, but fails to disclose the use of a visualization device or endoscope as claimed. However, Loiterman teaches that it was known to the art at the time the invention was made to use visualization devices and endoscopes with catheters; see column 1, lines 13-21. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to use a visualization device or endoscope with the Kaster method so that the progress of the operation could be more fully monitored making it safer and more efficacious.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster (US 5,366,819) in view of Ruppert (US 5,129,913). Kaster meets the claim language where the advancing step is disclosed on column 11, lines 37-43, and the instrument as claimed is the hole punch of Kaster that forms the hole for the anastomosis (see column 11, line 37 to column 12, line 38). It is noted that the order of the steps are not required to be the same as they are listed in the claim. Kaster fails to disclose the features of the hole punch. However, Ruppert teaches that hole punches of the art with lumens (sleeve

(11)) having a surgical device (rod (20)) were known; see the drawings and column 2, line 30 to column 3, line 11. Therefore, it is the Examiner's position that it would have been obvious to use the hole punch of Ruppert as the hole punch of Kaster to make a clean punch hole where longevity of the blade is desired; see the abstract of Ruppert.

***Allowable Subject Matter***

Claims 11 to 14 are allowed over the prior art of record.

***Response to Arguments***

Applicant's arguments filed September 30, 2005 have been fully considered but they are not persuasive.

Applicant argues that the double patenting rejection is not tenable because a step is missing from the copending claim that is present in the present claim. In response, the Examiner has maintained the obviousness-type double patenting rejection because copending claim 1 is still read on (present claim 9) or obvious over (present claim 7) the rejected claims. Claim 1 is broader such that it can be read on by present claim 9. For this reason, it is clearly obvious over claim 9 alone. Furthermore, claim 7 is clearly obvious because the teaching of Redtenbacher clearly shows that the only difference between the claims would have been obvious to an ordinary artisan.

Next, Applicants argue that claims 1-5 are not obvious over Brewster in view of Ablaza because it does not "establish blood flow outside the aorta or other blood vessel." However, the claims do not clearly require this. Furthermore, blood flow is established outside the aorta even if part of it is removed because the blood flow would

clearly go through the graft that is outside the natural aorta that is still present adjacent it; see Figure 55-6 on page 675.

Applicants also argue that entry is not below the inguinal ligament as required in claim 5. However, the positioning step of claim 5 does not clearly require that the blood conduit travel through the body from the initial entry to arteriotomy. Rather, the "initial entry" is merely "at a location relative to the femoral artery below the inguinal ligament." Since an entry point through the skin adjacent the aorta is "at a location relative to the femoral artery below the inguinal ligament", the claim language is considered fully met in this regard.

With regard to the rejections of claims 6-8 and 10, the Examiner asserts that the Applicant is attacking the secondary references as if they require all the limitations of the claim. Since the secondary references are merely teaching references and they have the feature missing from the base reference, the claim language is considered obvious thereover.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 3738